UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, NEW ENGLAND CARPENTERS HEALTH BENEFITS FUND, ALLIED SERVICES DIVISION WELFARE FUND, CHARLES C. FOTI, JR., in his Official Capacity as the Attorney General for the STATE OF LOUISIANA, as parens patriae on behalf of the STATE OF LOUISIANA and the CITIZENS OF THE STATE OF LOUISIANA, The STATE OF LOUISIANA, and the LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALSAND on behalf of themselves and all others similarly situated, **Plaintiffs,** v. **SANOFI-AVENTIS U.S. LLP, and SANOFI-AVENTIS U.S., INC.** **Defendants**	**CIVIL ACTION NO.** CV 08 179 **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED** TOWNES, J. MATSUMOTO, M.J.

Sergeants Benevolent Association Health and Welfare Fund ("SBA Fund"), New England Carpenters Health Benefits Fund ("NEC"), Allied Services Division Welfare Fund ("Allied Services"), Charles C. Foti, Jr., in his Official Capacity as the Attorney General for the State Of Louisiana, as *Parens Patriae* on behalf of the State of Louisiana and the Citizens of the State of Louisiana, the State of Louisiana, and The Louisiana Department of Health and Hospitals,

(collectively "Plaintiffs") individually, and on behalf of all others similarly situated, bring this action on behalf of itself and a class defined below. In its Complaint against Sanofi – Aventis ("Defendants" or "Sanofi"), Plaintiffs allege as follows based upon personal knowledge as to matters relating to itself and upon the investigation of counsel and information and belief as to all other matters.

I. INTRODUCTION

1. Plaintiffs bring this action, pursuant to Rule 23 of the Federal Rules of Civil Procedure, on their own behalf and as a representative of a class consisting of all health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit provider, including governmental entities, which paid or incurred costs for the drug Ketek.

2. This is a class action for damages brought by the Plaintiffs on behalf of a class of consumers and third-party payors that have paid or incurred costs for the drug Ketek. The drug was researched, designed, formulated, compounded, tested, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, or otherwise placed in the stream of interstate commerce by the Defendants. This action seeks, among other relief, general and special damages and equitable relief, including but not limited to recovery for prescription costs, restitution, refunds, and/or for equitable relief from Defendants.

3. Plaintiff, SBA Fund, is a citizen of the State of New York, and has its principal place of business at Worth Street, New York, New York. SBA Fund is an "employee welfare benefit plan" and an "employee benefit plan." As such, SBA Fund is a legal entity entitled to bring suit in its own name. SBA Fund is a not-for-profit benefit fund, sponsored by and administered by a Board

of Trustees, established and maintained to provide comprehensive health care benefits to participant-workers, who are employed under various collective bargaining agreements, and to their dependents. SBA Fund has paid all or part of the cost of its participants' purchases of Ketek during the class period, as defined herein. Plaintiff has been injured as a result of the unlawful conduct of Defendant as alleged herein.

4. Plaintiff, New England Carpenters Benefit Fund, is an employee welfare benefit plan established and maintained pursuant to §§ 1002(1) and (3) of ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. NEC maintains its principal place of business at 350 Fordham Road, Wilmington, MA 01887, and is involved in the business of providing health benefits for covered lives in the states of Massachusetts, Main, New Hampshire, and Vermont. Plaintiff NEC paid or incurred costs for prescriptions of Ketek dispensed to covered lives in several states.

5. Plaintiff, Allied Services, is a health and welfare benefit fund with its principal place of business at 53 West Seegers Road, Arlington Heights, Illinois 60005, and is involved in the business of providing health benefits for covered lives. Plaintiff Allied Services is a multi-employer employee welfare benefit plan, within the meaning of the Employee Retirement Income Security Act, 29 U.S.C. § 1001(2), and § 1002(37). Plaintiff Allied Services paid or incurred costs for prescriptions of Ketek dispensed to covered lives in several states.

6. Plaintiffs, Charles C. Foti, Jr., in his Official Capacity as the Attorney General for the State Of Louisiana, as *Parens Patriae* on behalf of the State of Louisiana and the Citizens of the State of Louisiana, the State of Louisiana, and The Louisiana Department of Health and Hospitals,

collectively represent the interests of the Louisiana Medicaid Program in this action and has paid or incurred costs for the payment for Ketek for Louisiana citizens.

7. Defendant Sanofi-Aventis U.S. LLC is a United States subsidiary of Sanofi-Aventis, SA , a French company, incorporated in Delaware, and headquartered in Bridgewater, New Jersey. During the relevant class period, the predecessor company, Aventis Pharmaceutical, Inc., was also headquartered in Bridgewater, New Jersey.

8. Defendant Sanofi-Aventis U.S., Inc. is a United States subsidiary of Sanofi-Aventis, SA , incorporated in Delaware, and headquartered in Bridgewater, New Jersey. During the relevant class period, the predecessor company, Aventis Pharmaceutical, Inc. was also headquartered in Bridgewater, New Jersey.

II. JURISDICTION AND VENUE

9. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (d)(2), which provides federal district courts with original jurisdiction over civil actions in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and is a class action in which "any member of a class of Plaintiffs is a citizen of a state different from any defendant."

10. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(a) because Defendant does business in this District and because a substantial portion of the improper conduct took place in this District.

11. Plaintiffs have filed this Complaint within one year since it discovered, or reasonably should have discovered by the use of reasonable care, any negligent, wrongful and/or culpable conduct and injury to the Plaintiff; and applicable tolling provisions apply.

III. FACTUAL ALLEGATIONS

12. This case involves the prescription antibiotic telithromycin, which was designed, formulated, patented, marketed, sold and ultimately distributed by the Defendants under the brand name Ketek. Ketek is used to treat respiratory infections, the largest market for antimicrobials. At the time of Ketek's approval, numerous, equally efficacious and cheaper antimicrobials were already available. Ketek merely allowed for additional option to treat drug-resistant bacterial infections.

13. Ketek's approval was the result of fraud, mismanagement and incompetence at all levels of the new drug approval process. When the full extent of the danger of Ketek was fully disclosed, the FDA removed two of the original three approved indications and required the addition of a black box warning, and the use of a once widely dispensed antibiotic was sharply curtailed.

14. In March 2000, Defendants submitted to the FDA the first new drug application to sell Ketek in the United States for four indications: community-acquired pneumonia, acute exacerbations of chronic bronchitis, acute sinusitis and tonsillopharyngitis. The FDA Advisory Committee assigned to review the application raised serious concerns about the safety of Ketek, particularly given suggestions of multiple risk factors and the likelihood of use by a wide population. Some of these concerns included interactions with other drugs, blurry vision and possible liver damage because the characteristics of Ketek resembled those of other drugs that had already been withdrawn from the market.

15. The FDA denied Defendants' application in June 2001 pending additional, more adequate safety studies which were to include a larger number of patients, target at-risk populations and examine wider drug interactions.

16. Starting in October 2001, Defendants purported to undertake such a study and hired Pharmaceutical Product Development, Inc. ("PPD"), a Contract Research Organization, to monitor the study. Known as study 3014, the study involved more than 1,800 physicians who ultimately claimed to have treated more than 24,000 patients in the regular course of clinical care. The study was an unblinded, randomized, controlled trial comparing the incidence rates for hepatic, cardiac and visual adverse events in patients receiving Ketek and those receiving amoxicillin-clavulanate, an available and already approved cheaper alternative treatment for the same indications as Ketek.

17. When Defendants submitted the results of study 3014 to the FDA on July 24, 2002, Defendants knew the study was severely tainted by fraudulent clinical practices. However, Defendants deliberately hid this fact from the FDA.

18. PPD contacted Defendants early in study 3014 with concerns about the integrity of the study. For example, on February 27, 2002, PPD warned Defendants that there were potential problems with the office treating the largest number of patients, the office of Dr. Marie "Anne" Kirkman Campbell. PPD noted, among other things, the lack of "proper diagnosis of an appropriate medical condition," "very limited" medical charts, and laboratory test results that were "suspiciously similar" for multiple patients. PPD also found that many patients signed on for the study during a time when Dr. Campbell's office was supposed to be closed.

19. PPD soon alerted Defendants about other doctors involved in the study. Indeed, PPD and Defendants were aware that study 3014 was marked throughout by violations of Good Clinical Practice ("GCP"), including simple, plainly evident matters like allowing doctors to enroll and treat patients far in excess of the limits governing the study, shoddy record keeping and overly rapid enrollment of patients, including many who should never have been in the study in the first place.

20. Although Defendants' manager overseeing study 3014 admitted to being uncomfortable with the many flaws in the study, Defendants ultimately submitted their report to the FDA on July 24, 2002, with all of the tainted data included, and with no caveats as to the integrity of study 3014. On the contrary, Defendants stated on the title page of their report to the FDA that the "study was conducted in accordance with good clinical practice and Aventis standard operating procedures for clinical investigation and documentation." When the FDA questioned Defendants about study 3014, Defendants assured the FDA as to the integrity the study 3014 and the established safety of Ketek.

21. In October 2002, the FDA began routine inspection of the highest enrolling office of study 3014, the office of Dr. Campbell (with 407 enrolled patients). The field investigator reported to the FDA's Office of Criminal Investigation ("OCI") "numerous regulatory deficiencies along with possible criminal violations." The OCI immediately reported the preliminary findings of its investigation to the United States Attorney: "it is believed Dr. Campbell falsified clinical trial results."

22. Subsequent investigations of Dr. Campbell, including consultations with PPD, confirmed: "enrollment of patients that were being seen for weightloss therapy, rather than conditions specified in the protocol," "documentation of patients as having completed courses of therapy despite statements from patients that they had not received medication," "enrollment of patients in numbers far in excess of that approved by the local IRB, without IRB review," and "enrollment of patients documents as being ineligible for the study on the basis of drug allergies." Within a month, Dr. Campbell was under formal criminal investigation for her conduct in study

3014 and received a 57 month sentence after pleading guilty to fraud in October 2003 in connection with study 3014.

23. Faced with such extensive misconduct in the study at Dr. Campbell's office, the FDA widened the inspection to include the second and third highest enrolling offices: Dr. Carl Lang with 251 enrolled patients and Dr. Ergisto Salerno with 214 enrolled patients.

24. On December 23, 2002, an FDA Division of Scientific Investigations ("DSI") official noted from the inspection of Dr. Lang's office "some similar problems found at [Dr.] Campbell. The issues were 251 subjects enrolled over the the [sic] max 50 recommended, enrolling study coordinator and his family, inadequate documentation ... and drug accountability log entries were not concurrent. Also, the site shipped laboratory samples incorrectly and numerous samples were beyond stability."

25. Dr. Salerno's investigation was initially hampered because he was on medical leave at the time due to a brain tumor. However, the investigator stated that "it appears that there may be problems with his study site too, even before starting the inspection." The investigator learned that Dr. Salerno had been disciplined in June 2001, just prior to his joining study 3014, by his state Medical Board for gross negligence and failure to maintain adequate and accurate medical records. He was placed on two years probation in part due to a problem with drug addiction and, in May 2002, had his license suspended.

26. Based on these preliminary indications of violations of GCP and fraud, an email exchange within the FDA on December 10, 2002, transpired as follows:

> Agent 1: "read these [DSI] messages. The validity of 3014 is growing more suspect by the day"

> Agent 2: "I think [the Division Director] agrees with us. While it might not go in the briefing document, it will eventually come back to haunt all parties involved – us if we do nothing, the public if the data is not trustworthy and the sponsor for not having disclosed these findings to us."

27. In January 2003, the FDA again declined approval of the NDA for Ketek, in large measure because of growing concerns with study 3014. The FDA requested additional evidence of the safety of Ketek and more information about study 3014. The FDA also requested initial incident reports from other nations where the drug had been approved.

28. Meanwhile, the investigatory arm of the FDA continued to widen its scrutiny of study 3014, ultimately inspecting the eight offices with the highest patient enrollments. The FDA's investigatory arm found no bottom to the fraud-plagued study. Specifically, the investigator ultimately reported on March 25, 2004, near the close of the investigation:

> Based on observations of non-compliance with FDA regulations and multiple instances of fraud detected at four of eight high-enrolling sites that FDA inspected, DSI recommends that data from sites 1129, [REDACTED], [REDACTED and [REDACTED] should be excluded from consideration in the NDA [New Drug Application]. In addition, the data from site 1057 is highly suspect since we consider that this clinical investigator was not qualified to perform the clinical trials. Monitoring of study sites by the sponsor/CRO failed to detect the significant problems found during the FDA inspections, calling into question the utility of the sponsor monitoring to detect data integrity problems. If the on-site monitoring of these eight sites did not detect the significant problems, there is no reason to expect that the on- or off-site monitoring of all other sites would have fared better at detecting significant problems. For these reasons, the integrity of data from all sites involved in stuffy 3014 cannot be assured with any degree of confidence.
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> FDA inspection of eight sites revealed numerous instances of non-compliance at each site. Although findings varied by site, the non-compliance included informed consent issues, protocol violations(i.e., enrolling ineligible subjects, safety laboratory results not obtained at all or not within the required time frames), inadequate and inaccurate record-keeping, non-reporting or late reporting of adverse effects to the sponsor, or not obtaining IRB approval for a research change (enroll more than 50 subjects). Specifically, the FDA inspection of site [REDACTED] revealed that many

> subjects had visit [sic] 2 safety laboratory tests performed well outside of the required interval; the FDA inspections of sites #1129 (Campbell), [REDACTED] and [REDACTED] raised serious concerns as to whether subjects existed, were eligible for the study, received study medication and completed the study. The latter three cases were referred to the Office of Criminal Investigations (OCI).

29. However, the final Advisory Committee never learned of the study, the fraud underlying it, or Defendants' complicity. Indeed, the Advisory Committee was never given the opportunity to properly weigh the risks of Ketek. Rather, the Advisory Committee was ultimately proffered only preliminary safety data from overseas and a handful of noninferiority trials which are not drug safety tests, but are only designed to gauge the maximum margin by which a new pharmaceutical (Ketek) may be less effective than an older intervention, but still beat a placebo. Based on this thin and sanitized record, the Advisory Committee voted to approve the NDA for Ketek for the treatment of acute bacterial sinusitis, acute bacterial exacerbations of chronic bronchitis and for the treatment of community-acquired pneumonia (of mild to moderate severity), for patients 18 years old and above. On April 1, 2004, Ketek entered the market.

30. After approval of Ketek, the overseas data for Ketek began to reflect the same severe events that would come to appear in the United States and the FDA concluded that the use of noninferiority trials was not justifiable in situations like the application of Ketek. The tainted study 3014 and the implications of the fraud surrounding that study, would eventually surface again in the course of a Congressional investigation of the FDA's role in allowing an unsafe drug like Ketek on the market. Indeed, in the course of this investigation, the Senate Finance Committee learned that most of the Advisory Committee members who voted to approve Ketek would never had done so if they had known the truth about the problems with study 3014 .

31. FDA documents conclude that Defendants hid Ketek's safety dangers from the FDA, dangers the FDA later discovered on its own. One FDA safety scientist, Dr. Cooper, wrote, "I tried to argue that given Aventis's track record in which they have proven themselves to be nontrustworthy that we have to consider the possibility that they are intentionally doing a poor job of collecting the postmarketing data to protect their drug sales."

32. In a press release on May 1, 2006 titled "Grassley Slams FDA For Citing Fraudulent Safety Study", Senator Charles E. Grassley, Chairman of the Senate Finance Committee, expressed his concern with the FDA's complicity with Defendants and the subsequent failure of the FDA to ensure the integrity of study 3014. The Senator identified a number of areas that were the focus of the Committee's investigation, including: a) accepting resubmission of the NDA which included fraudulent data; b) presenting fraudulent data to the advisory committee initially assigned to the NDA; c) instructing FDA scientists appearing before the advisory committee to present fraudulent data because discussing issues regarding data integrity would not be "productive"; d) continued use of the fraudulent data as part of publicly released safety information on Ketek. (Press Release, Senator Charles E. Grassley, "Grassley Slams FDA For Citing Fraudulent Safety Study" 5/01/06).

33. Ann Marie Cisneros was a senior clinical research associated at PPD who was assigned to monitor Dr. Anne Kirkman-Campbell's site for study 3014. Ms. Cisneros testified before the House Energy and Commerce Committee, Subcommittee on Oversight and Investigations on February 13, 2007:

> "Mr. Chairman, based upon what I observed and learned in monitoring the Kirkman-Campbell site, Dr. Kirkman-Campbell indeed had engaged in fraud. But what the court that sentenced her did not know is that Aventis was not a victim of this fraud. On the contrary....what brings me here today is my disbelief at Aventis's statements that it did not know that fraud was being committed. Mr. Chairman, I knew it, PPD knew it, and Aventis knew it."

34. Ms. Cisneros testified that even before conducting a site visit of the Kirkman-Campbell site, a number of "red flags" for fraud were apparent, including:

a) Ms. Cisneros knew that Dr. Kirkman-Campbell had enrolled over 400 patients or 1% of the adult population of Gadsden, Alabama, but that in comparison another site in Gadsden could only find and enroll just twelve patients that qualified for the study;

b) A Quality Assurance audit by Aventis noted several issues with Informed Consent, a significant under-reporting of Adverse Events, and no reports of Serious Adverse Events;

c) No patients had withdraw from the study and no patients were lost to follow up, which "just doesn't happen, period" given the number of subjects in the study;

d) Dr. Kirkman-Campbell had enrolled patients within minutes of each other and upwards of 30 patients per day; and

e) Dr. Kirkman-Campbell had enrolled patients at times and on days when her office was closed.

35. Upon reviewing patient charts during PPD's site visit to Dr. Kirkman-Campbell's site, they further discovered:

a) Every informed consent had a discrepancy;

b) Most of the consents looked like they had been initialed by someone other than the patient;

c) Many consents were dated by someone other than the subject;

d) One consent was blatantly forged;

e) There were date discrepancies as to when patients were enrolled in the study, had their blood drawn or signed their consent;

f) Most patients diagnosed with bronchitis either had no history of the ailment or did not have a "chronic" condition;

g) None of the staff would look Ms. Cisneros in the eye;

h) Medical records had been edited with notations of "sinusitis" and "bronchitis" added so patients would qualify for the trial; and

g) Dr. Kirkman-Campbell had enrolled her entire staff in the study.

36. Ms. Cisneros further testified that during her site visit, Dr. Kirkman-Campbell told Aventis Project Manager Nadine Guenthe that Ms. Cisneros would be allowed to stay only if Dr. Kirkman-Campbell was given other Aventis studies. During the FDA audit of Dr. Kirkman-Campbell's site in October 2002, Dr. Kirkman-Campbell was indeed working on another study for Aventis.

37. Ms. Cisneros further testified that Dr. Kirkman-Campbell told her she wouldn't have enrolled so many patients had Dr. Kirkman-Campbell known it would trigger an audit.

38. Ms. Cisneros communicated a summary of her site visit findings to Robert McCormick, head of quality assurance at PPD, and copied Aventis personnel. Furthermore, Ms. Cisneros discussed these issues directly in a teleconference between PPD and Aventis.

39. Certain she had found fraud, Ms. Cisneros took the unusual step of contacting the Copernicus Group Independent Review Board ("Copernicus"), also contracted by Aventis, responsible for ensuring patient safety in clinical trials. But, Copernicus deferred to Aventis and took no action.

40. Ms. Cisneros testified that in preparation for the October 2002 FDA audit of Dr. Kirkman-Campbell's site, Aventis Study 3014 Project Manager Nadine Guenthe coached Dr. Kirkman-Campbell with leading questions on how to explain away improper conduct.

41. Dr. Kirkman-Campbell herself stated that when the FDA called to schedule the audit, that Defendants told her to delay the auditing agent for a week. "Then they flew in two doctors to prep me and four to six girls to go through my files."

42. Dr. Kirkman-Campbell herself stated that Defendants "had been made aware of the fraud at my site by PPD. At no time did they attempt to stop my participation."

43. Defendants'' wrongdoing is not limited to its outright fraud on the FDA. Despite Ketek's approval for relatively narrow indications, Defendants engaged in a massive off-label marketing campaign designed to expand the market share across all segments of antimicrobial drugs. Despite its relatively narrow indications, Defendants lauded Ketek as the "next amoxicillin," widely used by millions of patients.

44. One part of Defendants' off-label marketing campaign included a nationwide program to pay certain physicians to attend "training" seminars to learn how to market Ketek to other physicians. In fact, in the summer of 2002, Defendants paid for Dr. Kirkman-Campbell to attend such a conference in San Diego.

45. Defendants' fraud and off-label marketing yielded great fruits for Defendants. Ketek had one of the most successful antibiotic launches in history. In 2005, Ketek was prescribed over 3 million times in the United States and reaped Defendants over $193 million in revenues. By 2006 Defendants had reaped $374 million in U.S. sales of over 6.1 million prescriptions.

46. Over 90% of Ketek prescriptions are written for unapproved or off-label indications.

47. Defendants' fraud also covered-up the immense risks unique to Ketek. In 2005, only seven months after the drug was introduced to the U.S. market, the first death from Ketek-associated liver failure was reported to the FDA.

48. On January 20, 2006, researchers reported three cases of severe liver toxicity following the use of Ketek. Of these cases, one patient needed a liver transplant and another died. Examination of these patients' livers showed massive tissue death. All patients had been healthy prior to the use of Ketek. By May 2006, FDA safety reviewers linked Ketek to 12 reported liver failures including 4 deaths, 23 reports of serious liver injury and a higher rate of adverse reaction reports than other antibiotics on the market. The FDA ordered the strengthening of the warnings in Ketek's label in June 2006 to include a risk of liver damage. By the end of 2006, Ketek had been implicated in 53 cases of hepatotoxic effects.

49. A recent analysis of the FDA's post-marketing database showed that the rate of reporting of acute liver failure was 3.5 to 11 times higher for Ketek than for other antibiotics, with a reporting rate of 167 cases of acute liver failure per one million person-years of telithromycin use as compared with the expected rate of one case per one million person-years.

50. On February 12, 2007, on the eve of a formal Congressional hearing on the FDA's handling of the Ketek NDA, the FDA withdrew approval for two of Ketek's indications: acute bacterial sinusitis and acute exacerbation of chronic bronchitis, for which Ketek's efficacy had never been demonstrated. Further, the FDA increased the magnitude of warning for at least one of its risks, elevating this warning to a "boxed" warning, the severest warning available.

51. Prior to Defendants' February 2007 addition of the black box warning, U.S. doctors wrote an estimated 6 million prescriptions for Ketek, a drug that should never have been marketed

for most of its initial indications and that has never been shown to be more efficacious than cheaper and safer alternatives.

52. The effect of Defendants' wrongful conduct was payment by the Plaintiffs and the class members for Ketek prescriptions that otherwise would not have been paid for and the payment of higher prices for Ketek than the drug would have commanded absent the fraud on the medical and scientific community, consumers and the third-party payors.

IV. CLASS ACTION ALLEGATIONS

53. Plaintiffs bring this action, pursuant to Rule 23 of the Federal Rules of Civil Procedure, on their own behalf and as a representative of a class consisting of all health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit provider, including governmental entities, which paid or incurred costs for the drug Ketek.

54. Plaintiffs and the Class bring this action for equitable relief and damages pursuant to Federal Rule of Civil Procedure 23(b)(2) and 23(b)(3).

55. Plaintiffs and the Class seek a refund or reimbursement of all amounts they have expended for the purchase of Ketek; and, all other ascertainable economic losses and such other relief as the Plaintiffs and the Class are entitled to, including treble damages and reasonable attorneys' fees and costs.

56. Plaintiffs are members of the class it seeks to represent. The Class is believed to number in the thousands. As a result, joinder of all Class members in a single action is impracticable.

57. There are questions of law and fact common to the members of the Class, including but not limited to:

- Whether Plaintiffs and the class paid more for Ketek than for other efficacious drugs that were available at a cheaper price;
- whether persons who took Ketek are at increased risk of severe and permanent injuries, including liver damage and/or failure, cardiac damage and visual impairment and damage;
- whether, in marketing and selling Ketek, Defendants failed to disclose the dangers and risks to the health of persons ingesting the drug;
- whether Defendants failed to warn adequately of the adverse effects of Ketek;
- whether Defendants misrepresented in their advertisements, promotional materials and other materials, among other things, the safety, potential side effects and convenience of Ketek;
- whether Defendants knew or should have known that the ingestion of Ketek leads to serious adverse health effects;
- whether Defendants adequately tested Ketek prior to selling it;
- whether Defendants manufactured, marketed, distributed and sold Ketek notwithstanding their knowledge of the drug's dangerous nature;
- whether Defendants knowingly omitted, suppressed and/or concealed material facts about the unsafe and defective nature of Ketek from government regulators, the medical community and/or the consuming public;
- whether Defendants engaged in a misleading and/or deceptive scheme of improperly marketing and selling Ketek for conditions for which it is not safe or medically efficacious;
- whether Defendants engaged in a misleading and/or deceptive scheme of improperly marketing and selling Ketek to treat conditions for which the drug was not approved or should not have been approved by the FDA;
- whether Defendants are liable to the Class Members for damages for conduct actionable under various Consumer Protection Statutes of the United States;

- whether Defendants unjustly enriched themselves at the expense of Class Members;
- whether Defendants engaged in a pattern or practice that directly caused Plaintiffs and Class Members to pay for Ketek prescriptions that were non-medically necessary uses;
- whether Defendants engaged in deceptive and/or misleading activity that directly caused Plaintiffs and the Class to pay for Ketek prescriptions that were for non-FDA approved uses; and
- whether Defendants engaged in deceptive and/or misleading activity with the intent to defraud Plaintiffs and the Class.

58. These and other questions of law and/or fact are common to the Class and predominate over any question affecting only individual class members.

59. The claims of the class representatives are typical of the claims of the Class in that the named class representatives and the members of the Class each paid for the prescription drug Ketek or reimbursed members for the costs of the prescription due to the improper actions of the Defendants, as described herein.

60. Plaintiffs know of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action.

61. Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained counsel competent and experienced in complex class actions and products liability litigation to represent the Plaintiffs and the members of the proposed Class. Accordingly, the interests of the Class will be adequately protected and advanced. In addition, there is no conflict of interest between the representatives of the proposed Class and members of the Class.

62. Maintenance of this action as a class action is a fair and efficient method for adjudication of this controversy. It would be impracticable and undesirable for each member of the Class who has suffered harm to bring a separate action. In addition, the maintenance of separate

actions would place a substantial and unnecessary burden on the courts and could result in inconsistent adjudications, while a single class action can determine, with judicial economy, the rights of all class members.

63. Notice can be provided to class members by using techniques and forms of notice similar to those customarily used in other drug-related products liability cases and complex class actions.

64. Certification of the Class is appropriate pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3) because the questions of law and fact common to members of the Class predominate over any questions affecting only individual members. This class action is superior to other available remedies for the fair and efficient adjudication of this controversy.

V. CAUSES OF ACTION

COUNT I: VIOLATIONS OF STATE CONSUMER PROTECTION STATUES

65. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

66. Defendants intended that Plaintiffs, the Class and the medical and scientific community would rely on their materially deceptive practices and Plaintiffs and the class would purchase or pay for Ketek as a consequence of the deceptive practices, including Defendants' off-label marketing and misrepresentations and omissions of material fact with respect to Ketek as set forth herein. Defendants' deceptive representations and material omissions to Plaintiffs and the Class were and are unfair and deceptive acts and practices. Plaintiffs and the Class were deceived by Defendants' misrepresentations. As a proximate result of Defendants' misrepresentations, Plaintiffs and the Class have suffered an ascertainable loss, in an amount to be determined at trial, in that they

paid millions of dollars for Ketek that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

67. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of ARIZ. REV. STAT. § 44-1522, *et seq.*

68. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of ARK. CODE ANN. § 4-88-107, *et seq.*

69. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of CAL. BUS. & PROF. CODE § 17200, *et seq.*

70. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or have made false representations in violation of COLO. REV. STAT. § 6-1-101, *et seq.*

71. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of CONN. GEN. STAT. § 42-110b, *et seq.*

72. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of DEL. CODE ANN. tit. 6, § 2511, *et seq.*

73. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. CODE ANN. § 28-3901, *et seq.*

74. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of FLA. STAT. ANN. § 501.201, *et seq.*

75. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of GA. CODE ANN. §10-1-392, *et seq.*

76. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of HAW. REV. STAT. § 480, *et seq.*

77. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of IDAHO CODE § 48-601, *et seq.*

78. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILL. COMP. STAT. 505/2, *et seq.*

79. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of IND. CODE ANN. § 24-5-0.5-1, *et seq.*

80. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of KY. REV. STAT. ANN. § 367.110, *et seq.*

81. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of LA. REV. STAT. ANN. tit. 15, § 1401, *et seq.*

82. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of ME. REV. STAT. tit. 5, § 205-A, *et seq.*

83. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of MD. CODE. ANN., COM. LAW § 13-101, *et seq.*

84. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation MASS. GEN LAWS ch. 93A, §1, *et seq.*

85. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of MICH. COMP. LAWS § 445.901, *et seq.*

86. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of MINN. STAT. § 8.31, *et seq.*

87. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of MO. REV. STAT. § 407.010, *et seq.*

88. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of NEB. REV. STAT. § 59-1601, *et seq.*

89. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of NEV. REV. STAT. 598.0903, *et seq.*

90. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. REV. STAT. ANN. § 358-A:1, *et seq.*

91. Defendants have engaged in unfair competition or deceptive acts or practices in violation of N.J.S.A. § 56:8-1, *et seq.*

92. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. STAT. ANN. § 57-12-1, *et seq.*

93. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. GEN. BUS. LAW § 349, *et seq.*

94. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. GEN. STAT. § 75-1.1, *et seq.*

95. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. CENT. CODE § 51-15-01, *et seq.*

96. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of OHIO REV. CODE ANN. § 1345.01, *et seq.*

97. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of OKLA. STAT. tit. 15, § 751, *et seq.*

98. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of OR. REV. STAT. § 646.605, *et seq.*

99. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 PA. CONS. STAT. § 201-1, *et seq.*

100. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. GEN. LAWS § 6-13.1-1, *et seq.*

101. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. CODIFIED LAWS § 37-24-1, *et seq.*

102. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of TENN. CODE ANN. § 47-18-101, *et seq.*

103. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of TEX. BUS. & COM. CODE ANN. § 17.41, *et seq.*

104. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of UTAH CODE. ANN. § 13-11-1, *et seq.*

105. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of VT. STAT. ANN. tit. 9, § 2451, *et seq.*

106. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of VA. CODE ANN. § 59.1-196, *et seq.*

107. Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of WASH. REV. CODE § 19.86.010, *et seq.*

108. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. VA. CODE § 46A-6-101, *et seq.*

109. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of WIS. STAT. § 100.18, *et seq.*

110. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of WYO. STAT. ANN. § 40-12-101, *et seq.*

111. The unfair and deceptive acts and practices of Defendants have directly, foreseeably and proximately caused or will cause damages and injury to Plaintiffs and the members of the Class.

112. The actions and failures to act of Defendants, including the false and misleading representations and omissions of material facts regarding the side effects and the off-label use(s) for Ketek and the above described course of fraudulent conduct and fraudulent concealment, constitute acts, uses, or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression, or omission of material facts in connection with the sale of merchandise of Defendants in violation of the consumer protection statutes listed above

113. Physicians relied upon Defendants' misrepresentations and omissions in prescribing Ketek to patients. Defendant's misrepresentations and omissions caused Plaintiffs and others similarly situated to pay for Ketek. By reason of the unlawful acts engaged in by Defendants, Plaintiffs and the Class have suffered ascertainable loss and damages. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the Class were damaged by paying for these prescriptions.

114. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and members of the Class are entitled to compensatory damages, treble damages, attorneys' fees and costs of suit.

COUNT II: UNJUST ENRICHMENT

115. Plaintiffs incorporate the allegations of the foregoing paragraphs by reference.

116. As an intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants profited and benefited from payments Plaintiffs and the Class made for Ketek.

117. In exchange for the payments they made for Ketek and at the time it made these payments, Plaintiffs and the Class expected that the drug was a safe and medically effective treatment for the condition, illness, disorder, or symptom for which it was prescribed.

118. Defendants voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs and the Class paid for Ketek when they otherwise would not have done so and paid for the drug at a higher price than they would have paid but for the Defendants' wrongful conduct.

119. Plaintiffs and the Class are entitled in equity to seek restitution of Defendants' wrongful profits, revenues and benefits to the extent and in the amount, deemed appropriate by the Court and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

DEMAND FOR RELIEF

WHEREFORE, Plaintiffs and the Class demand judgment against Defendants in each claim for relief, jointly and severally, as follows:

a) For an order certifying this matter as a class action as requested herein and a declaration that this action is a proper class action pursuant to Federal Rule of Civil

Procedure 23, establishing an appropriate class or classes and finding that the Plaintiffs and their counsel are proper representatives of the class;

b) For an Order appointing the undersigned counsel as Class counsel;

c) On Plaintiffs' and the Class's Consumer Fraud Act claims, compensatory damages, and enhancement of damages Plaintiffs and the Class have sustained as a result of Defendants' conduct as may be permitted under the relevant statutes, such an amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;

d) On Plaintiffs' and the Class's claim for unjust enrichment, recovery in the amount of Plaintiffs' and the Class's payment for Ketek, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including all reasonable attorneys' fees;

e) For an order otherwise requiring Defendants to refund and make restitution of all monies acquired from the sale of Ketek to Plaintiffs and the Class;

f) Awarding Plaintiffs and the Class prejudgment interest on all damages;

g) Awarding Plaintiffs and the Class other appropriate equitable relief;

h) Awarding Plaintiffs and the Class their costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

i) Awarding Plaintiffs and the Class such other and further relief as may be just and proper under the circumstances.

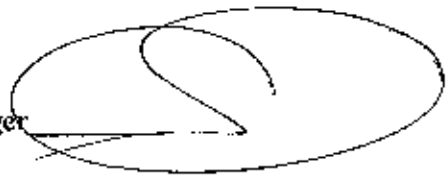
JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand trial by jury on all issues so triable.

Dated: January 14, 2008

Respectfully submitted,

SEEGER WEISS, LLP



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